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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,340	09/29/2000	John R. Subject	126.1-US-U3	2180

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 09/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER
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Commissioner for Patents

Advisory Action

Application No.

09/676,340

Applicant(s)

SUBJECK ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): See attached Note of Explanation.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached Note of Explanation.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-10, 16-23, 33, 34, and 46-69.

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☒ Other: See attached Note of Explanation.

Note of Explanation

1. The amendment filed July 8, 2003 in Paper No. 15 is acknowledged and has been entered into the record; however, the proposed amendments to the claims have not been entered for the following reasons:

The proposed amendments to the claims will not be entered, because entry of the amendment would raise new issues that would necessitate further consideration and possibly further search. The reason that entry of the amendment would raise new issues, which would require further consideration, is the merit of claims 46-57 would have to be considered. As the claims were originally presented, the claims depended from cancelled claim 32; therefore, as set forth in section 7.C. of the Office action mailed April 8, 2003 (Paper No. 14), the claims were rejected under 35 USC § 112, second paragraph, because the nature, and metes and bounds of the invention could not be determined, but claims 46-57 were not otherwise considered during the open prosecution of this application. The examination of claims 46-57 under 35 USC §§ 101, 112, first paragraph, 102, and 103 would need be performed if the amendment were to be entered. As claim 32 had been drawn to a non-elected invention, the proposed amendment, if entered would amend claims 46-57 so as to be drawn to the elected invention, albeit the scope of the claims would differ from the scope of the examined claims. Therefore, for this reason also, entry of the amendment would necessitate further consideration and search. Accordingly, the entry of the proposed amendment would not place this application in better form for appeal by materially reducing or simplifying the issues for appeal.

2. Applicants' grounds of traversal of the claim rejections set forth in the final Office action mailed April 8, 2003 (Paper No. 14) has been carefully considered and found persuasive in part. Accordingly, the following grounds of rejection set forth in the final Office action have been withdrawn:

(a) The rejection of claim 16 under 35 USC § 112, first paragraph for the reason set forth in section 5.A. of the final Office action.

(b) The rejection of claims 33 and 34 under 35 USC § 112, first paragraph for the reason set forth in section 5.C. of the final Office action. Indeed, literal support for the limitation

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“antitumor immune response” can be found at page 15, lines 15-23; nonetheless, for clarity of record, it is noted that the specification does not appear to describe a method effective to elicit an immune response comprising, for example, an antitumor humoral immune response. Instead, the disclosure at page 5, line 3, to which the Examiner referred in the final Office action, and the disclosure at pages 48 to 49, to which Applicants have referred in their arguments filed July 8, 2003, suggest that the claimed method may only be sufficient to elicit an antitumor CTL immune response.

3. It is noted that had the amendment been entered, entry of the amendment would have obviated the following grounds of rejection set forth in the final Office action mailed April 8, 2003 (Paper No. 14):

(a) The rejection of claim 7 under 35 USC § 112, first paragraph for the reason set forth in section 4 of the final Office action.

(b) The rejection of claim 7, 21, 46-57, and 67 under 35 USC § 112, second paragraph for the reasons set forth in section 7 of the final Office action.

4. Applicants’ arguments, otherwise, have been carefully considered but not found persuasive to overcome the remaining grounds of rejection set forth in the final Office action mailed April 8, 2003 (Paper No. 14) for the following reasons:

The Examiner disagrees with Applicants’ assertion that the disclosure at page 25 provides proper and sufficient antecedent basis for the breadth of claims 19, 20, 65, and 66. Applicant is reminded that it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See *In re Smith*, 173 USPQ 679, 683 (CCPA 1972). Considering the disclosure at page 25, it is clear that Applicants have described a genus of her-2/neu peptides and more specifically described members of this genus, namely “the intracellular domain of her-2/neu (amino acid residues 676-1255 [...], p369 (also known as E75; KIFGSLAFLI SEQ ID NO: 6) of the extracellular domain of her-2/neu, and p546, a transmembrane region of her-2/neu (VLQGLPREYV; SEQ ID NO: 5)” (Specification, paragraph bridging pages 25 and 26). However, this disclosure does not provide a proper and sufficient basis to support the recitation of a limitation in the claims requiring the her-2/neu peptide to be

“derived from the extracellular domain of her-2/neu” (claims 19 and 65) or alternatively, “derived from the transmembrane region of her-2/neu” (claims 20 and 66).

Regarding the rejection of claims under 35 USC § 102, Applicants have reiterated arguments set forth previously. In particular, Applicants have again argued that none of the cited references teach a pharmaceutical composition comprising a stress protein complex comprising hsp110 and an immunogenic polypeptide, or even that hsp110 has therapeutic properties. Furthermore, Applicants have argued that it cannot be presumed that all stress proteins are capable of functioning as an effective component of a vaccine, as the specification teaches that grp78 is not immunogenic at page 48, lines 7-10.

In reply, the example set forth in the specification teaches mice were injected with “tumor or liver derived hsp110 or grp170” (Specification, page 47, line 9) and “grp170 appears to be more immunogenic than hsp110” (page 48, line 8). The specification further discloses, “grp78 is either not immunogenic, or is so at a low level only” (page 48, lines 9 and 10). Although Applicants disclose that grp78 is not as immunogenic as hsp110, at column 3, lines 10-24, US Patent No. 5,891,432-A (‘432) teaches a cellular vaccine comprising a membrane-bound fusion protein that includes an immunomodulatory molecule, which can be immunostimulatory. At column 6, lines 58-67, ‘432 teaches that heat shock proteins, including HSP110, are immunomodulatory molecules useful in the vaccines. ‘432 does not specifically teach that grp78 is useful in the vaccine. Thus, contrary to Applicants’ argument that ‘432 teaches that hsp110 could be used as a component of an effective vaccine, as hsp110 is has immunostimulatory properties.

Regarding the rejections of the claims under 35 USC § 102, as being anticipated by US Patent Nos. 5,747,332-A (‘332) and 6,066,716-A (‘716), Applicants have argued that the patent does not teach that hsp110 is immunogenic. In reply, ‘332, for example, teaches a pharmaceutical composition comprising a heat shock protein complex, which can be derived from tumor cells and which comprises hsp110 and an immunogenic polypeptide. Moreover, at column 1, lines 13-15, for example, ‘332 teaches that such heat shock protein complexes were previously recognized as being useful in vaccines against cancers and infectious diseases. Contrary to Applicants’ assertions, the immunogenic properties of the heat shock proteins were well known. ‘332 teaches, “there are many heat shock proteins that may be used in the method of

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the present invention" and "heat shock proteins that have proven particularly useful include members of the [...] hsp104-105 family" (column 3, lines 48-52). '332 teaches: "Members of the hsp104-105 family include hsp105 and hsp110" (column 3, lines 66 and 67).

Applicants' have reiterated the grounds of traversal of the rejection of the claims under 35 USC § 103, which were first set forth as part of the amendment filed December 9, 2002. The reasons that Applicants' arguments were not found persuasive have already been set forth in the final Office action mailed April 8, 2003 (Paper No. 14).

In summary, the Examiner disagrees with Applicants' assertions that the claimed invention is not anticipated under 35 USC § 102, or otherwise rendered obvious under 35 USC § 103 by the prior art cited as the basis of the claims rejections.


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
September 4, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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